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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,519	09/17/2003	Rabih O. Darouiche	124169-1010 (OTA 02-036	4877

37058 7590 12/08/2006

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EXAMINER	
JAWORSKI, FRANCIS J	

ART UNIT	PAPER NUMBER
3768	

DATE MAILED: 12/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/664,519	DAROUICHE ET AL.	
	Examiner	Art Unit	
	Jaworski Francis J.	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 September 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☒ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 - 9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1 - 9* is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 September 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Specification/Drawings

In general, the specification and the drawings must be internally self-consistent, with the specification discussing all legends depicted in the drawings and the drawings showing every claimed feature in a manner which is consistent among views and meets drawing requirements of 37 CFR 1.83 and 1.84.

1) The specification is objected to insofar as the inclusion of numbers from referenced patents creates confusion as to whether the discussion legends pertain to applicants' Figures or to Figures elsewhere. Therefore it is requested that the applicants revise the specification to include a sentence referring to the respective patent's feature of interest without introducing the associated reference numerals.

2) The specification must also provide a complete description of the drawings insofar as they depict claimed features, and must be technically accurate. Certain revisions are required as a result of required drawing revisions provided below.

3) With respect to the drawings, the severality of views must be consistent and be technically accurate.

In **Figure 1:**

- the central breathing bore is a large diameter bore as shown in applicants' figure 3 and therefore cannot be a narrowed passageway as shown in the upper "16" designation in Fig. 1. Such a narrow passageway is typically the inflation channel for the catheter anchoring

balloon such as shown as element 4 in the face figure of Turner (US5638812) and is for example extruded within the tubing of the device.

- This in turn is an oblique way of saying that applicants' multi-lumen construct is tri-partite. A wide central bore supports the patient's breathing; an anti-microbial/anti-biofilm lumen supports delivery of these agents to distal ports 18, and an inflation lumen supports inflation of the regional anchoring or cuff balloon 30 with inflation integrity (no cross-leakage) to the other two lumens.
- The therapeutic agent delivery ports 18 should be shown in this view as well as ultrasound port 20 and electrical port 22 (which is currently depicted nowhere) since they would appear in this view.
- Since the ports need be shown, the ultrasound and electrical current devices occupying these ports need be shown since they are claimed as 'means' in the base claim and essential for patentability, therefore requiring that the drawings provide a depiction since they would be seen in this longitudinal surface view.

In **Figure 2:**

- The depiction of the cuff is confusing since it is a distal airway centering anchor in the Fig. 1 view which shows 30 as regionalized.

  Since ports 18 exit distally and the lumen to 30 must have fluid integrity, these ports must have their supply channels shown in this longitudinal view. It is unclear how these therapeutic agents are otherwise delivered

to lavage the device exterior without gagging the patient.

Ports 20 and also 22 should be shown in this view since they would appear in cross-section. Also the ultrasound/current applicator devices should be generically shown, e.g. as button-elements or labeled points.

Additionally, it is inconsistent that the device come to a 'point' in fig.2 but appear as a slant cut in fig. 1.

Also, legend 20 currently points to neither a port nor a button-element/point.

The holes entering the balloon interior should be labeled.

Finally, the cut-plane relating Fig.3 to either Fig. 1 or 2 or both should be shown.

In **Fig. 3**:

The elements 18 and 30 cannot appear together if this is a cut view, since there is no radial slice plane across the device axis that contains both.

On the other hand, if Fig. 3 is an end-view in the analogy sense of one gazing at either end of a flute, then the fingerholes would not be visible since they are depressions with no radial relief beyond the tube wall 14, whereas at least one of 20, 22 would in the sense of being end-located.

Note that no new matter may be introduced into a patent application after its filing. Therefore alterations are limited to verbalizing what is schematized in drawings and vice-versa or to correcting obvious error

in conventional manner, or for example by generically referring to the patents cited for implementation specifics beyond any non-specific descriptions/depictions used to remedy the inconsistencies listed above.

Allowable Subject Matter

Claims 1 – 9 are allowed.

The Miller et al patent (US688727) teaches that one may apply a biofilm inhibitor to a catheter as well as an anti-microbial agent in order to reduce indwelling morbidity, since the biofilm is otherwise typically a matrix comprised of polysaccharide or proteinaceous and glycoprotein materials which coats the microbial mass and interferes with the action of anti-microbial agents.

Weiss (US6428491) teaches the use of an ultrasound device integral with a catheter in conjunction with anti-biofilm coatings and therapeutic agent delivery but not in a context supportive of airway usage.

Marais (US6878287) teaches the use of AC current as an alternative to ultrasound for purposes of cleaning biofilms.

This application is in condition for allowance except for the formal matters discussed above..

Prosecution on the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

A shortened statutory period for reply to this action is set to expire **TWO MONTHS** from the mailing date of this letter.

Any inquiry concerning this communication should be directed to Jaworski Francis J. at telephone number 571-272-4738.

FJJ:fjj

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Francis J. Jaworski
Primary Examiner